

REMARKS**I. Status of the Claims**

Claims 1, 3, 5, and 10 are canceled.

Claims 2, 7, 8, 9, and 11 are amended.

Claims 2, 4, 6-9, and 11 are pending.

II. Pending Claims Satisfy 35 U.S.C § 112**A. Amended Claim 11 Obviates Examiner's 112 Rejections**

On page 3 of the Action, the examiner rejected claim 11 under 35 U.S.C § 112 first paragraph. On page 4 of the Action, the examiner admits that "literal support for the enzymes are present in a working example" and "the enzymes were used in a specific assay".

On page 9, lines 16-23, the specification discloses:

The M307 transition eliminates a restriction site for CfoI. Amplification of DNA isolated from porcine nucleated cells was performed according to standard procedures with primers P6 and P11 (3 min at 95°C., 30 cycles of 30 sec at 95°C., 30 sec at 56°C. and 30 sec at 72°C., followed by a 7 min final extension at 72°C.) followed by CfoI digestion and separation on a 3% agarose gel resulted in a restriction fragment length polymorphism (RFLP). Homozygous M307^{AA} animals showed 2 bands. Homozygous M307^{GG} animals showed 93-, 241- and 87 bp fragments. Heterozygous animals showed all four fragments.

Contrary to the examiner's assertions on page 4 of the Action, the specification teaches a specific use (*i.e.*, identifying the M307 mutation) and the amplified-restricted products represent the polymorphism in the FUT1 gene and its association for resistance to *E. coli* infection. Example 1 (page 9 of the specification) adequately describes the products (generated by CfoI) of claim 11 and also teach a specific use of identifying the M307 mutation. Recognizing the restricted fragments of amplified FUT1 gene through standard hybridization techniques represents a specific use.

On page 11, line 32 through page 12, line 4, the specification discloses:

The M857 mutation is a transition that eliminates an AclI site. Primer PBEST was designed to mismatch two additional AclI sites at positions 866 and 872. PCR with primers P7 and PBEST (3 min

at 95°C., 30 cycles of 30 sec at 95°C., 30 sec at 56°C. and 30 sec at 72°C., followed by a 7 min final extension at 72°C.) followed by *AciI* digestion enables PCR-RFLP analysis on a 3% agarose gel. Homozygous M857^{AA} animals show a 174 bp fragment while amplification products of M857^{GG} animals show 136- and 38-bp fragments.

Example 7 (pages 11-12 of the specification) adequately describes the products (generated by *AciI*) of claim 11 and also teach a specific use of identifying the M857 mutation. Recognizing the restricted fragments of amplified FUT1 gene through standard hybridization techniques represents a specific use.

Claim 11 is amended to include “swine” and is rewritten for clarity to indicate that the nucleic acid fragments of FUT1 are produced by amplification followed by restriction. Therefore, the specification provides adequate support for claim 11 and the amendment filed June 27, 2003 to include claim 11 did not include new matter. Applicants request that the 112 rejection of claim 11 be withdrawn.

B. Amended Claims 2, 4, 6-9, 11 Satisfy 35 U.S.C § 112 First Paragraph Requirements

On pages 5-8, the examiner rejected claims 2, 4, 6-11 under 35 U.S.C § 112 first paragraph. On page 6 of the Action, the examiner stated:

In the instant case, while the specific SEQ ID NO: 12 and the specific sequence at position 307 are adequately set forth, outside these specific sequences lacks written description. It is noted that the specification contemplates other sequences and use thereof however the specification fails to provide any description or clear guidance to what these genes would be, and more specifically, what sequences are comprised within these claims.

Applicants are unclear as to what the examiner refers as “other sequences” and “what these genes would be”, because the pending claims to refer to FUT1 gene or SEQ ID NO: 12. For clarity, SEQ ID NO: 12 is included in claims 8 and 9. Claim 7 is amended to state that the *E. coli* is *E. coli* F18.

On page 10, the examiner stated that “claims 8 and 9 are unclear in the recitation of the metes and bounds of the probe”. Claims 8 and 9 are amended to include “nucleic acid probe derived from SEQ ID NO: 12”. Support for nucleic acid probes can be found at least on page 10,

line 15-17, page 16, lines 19-21, and page 17, lines 7-8. Applicants believe that claims 8 and 9 are now in allowable form.

On page 7 of the Action, the examiner stated that the “mechanism of action or resistance is not known or described”. The pending claims relate to isolated nucleic acids and not to mechanisms of actions or resistance. The disclosed polymorphisms are useful in identifying disease resistance in swine. The markers represent a correlative analytical tool to identify swine that are resistant to *E. coli* colonization. Mechanism of action of resistance is not required by the scope of the pending claims nor by statute.

C. Pending Claims 35 U.S.C § 112 Second Paragraph Requirements

On page 9 of the Action, the examiner rejected claims 2, 4, 6-11 under 35 U.S.C § 112 second paragraph. Claim 2 is amended to clarify that the claimed product comprises SEQ ID NO: 12 or its M307 variant. Claims 8 and 9 are amended for clarity. Claim 10 is canceled. Claim is rewritten for clarity as the examiner suggested.

Therefore, the applicants believe claims 2, 4, 6-11 are in allowable form and request the 112 second paragraph rejection be withdrawn.

III. Pending Claims are Not Anticipated by US Pat. No. 6,355,859

On page 11 of the Action, the examiner rejected claims 2, 4, 6-10 under 35 U.S.C § 102 (f). The examiner stated:

The instant application and US Patent 6,355,859 share one common inventor and no common assignee.

However, as shown on the cover sheet of the patent, the instant application and US Patent 6,355,859 share at least one common assignee—Biotechnology Research and Development Corporation. According to MPEP § 706.02(g) the examiner must presume the applicants are the proper inventors unless there is proof that **another** made the invention and that the applicant derived the invention from the true inventor. In the instant application, there is no proof that Bosworth and Vögeli are not the true inventors. Therefore the applicants request the 102 (f) rejection be withdrawn.

IV. Pending Claims in the Present Application are Patentably Distinct from the Claims of U.S. Pat. No. 6,355,859 and U.S. Pat. No. 6, 596, 923

On page 12 of the Action, the examiner rejected claims 3 and 4 under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Pat. No. 6,355,859.

It is unclear as to which claims 3 and 4 the examiner is referring to because, claim 3 was previously canceled and claim 4 does not refer to any method. On page 12 of the Action, the examiner states:

In the instant application, claims are drawn to a method for identifying a swine that is resistant to intestinal colonization to a of strain of *E. coli* associated intestinal disorders by determining whether base pair 307 of the open reading frame of FUT1 is an adenine, and in particular the *E. coli* is strain ECF18R.

However, pending claims in the present application relate to polynucleotides and not to methods of identifying resistant swine. The '859 patent relates to an entirely different invention. The '859 patent relates to a method of **improving weight gain** in swine that are susceptible to F18 *E. coli* colonization by matching diet with phenotype.

On page 13 of the Action, the examiner rejected claims 3-6 under the doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Pat. No. 6,596,923.

Claims 3 and 5 were previously canceled and it is unclear as to which claims 3-6, the examiner is referring to. The examiner refers to "the instantly claimed methods set forth in claims 3 and 4" (page 13 of the Action). The present application is a divisional of U.S. Serial No. 09/443,766 filed November 19, 1999, now U.S. Pat. No. 6,596,923. Claim 1 of the '923 patent relates to a method of identifying a swine that is resistant to *E. coli* infection, whereas the pending claims in the present application relate to polynucleotides, which were acknowledged as a separate invention by being classified in a different restriction group (Group III).

Therefore, the applicants believe the double patenting rejection is improper and request that the obviousness-type double patenting rejections be withdrawn.

V. Conclusion

In a telephone call, the examiner mentioned that an IDS had not been received by him. A copy of the IDS that was filed earlier is resubmitted along with this response for the examiner to

consider. Applicants request that the pending claims be allowed. A telephone interview is requested to expedite the prosecution if there are remaining issues.

No fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (21459/91513).

Respectfully Submitted,

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CHDS01 AOM 224155v1